

NOV - 8 2000

**510(k) Summary of Safety and Effectiveness  
for  
Agilent Technologies, Inc.**

**M2662A Handheld Electrocardiograph**

1. **DATE SUMMARY PREPARED** August 1, 2000
2. **SUBMITTER'S NAME AND ADDRESS** Agilent Technologies, Inc.  
Healthcare Solutions Group  
3000 Minuteman Road  
Andover, MA 01810-1099
3. **CONTACT PERSON** Rob Butler  
Regulatory Affairs Manager  
Telephone: (978) 659-2785  
Facsimile: (978) 687-8284
4. **DEVICE NAME** Proprietary Name: PageWriter 10/10I  
Common Name: Electrocardiograph  
Classification Name: Electrocardiograph, CFR 870.2340

M2662A also includes software that constitutes an "ECG Analysis System" (product code LOS)

1. **PREDICATE DEVICE** The legally marketed devices to which equivalence is being claimed is the M1770A electrocardiograph manufactured by Agilent Technologies, Inc. (formerly Hewlett-Packard Co.) – K935772
2. **DEVICE DESCRIPTION** The Model M2662A Handheld Electrocardiograph is a low-cost, portable electrocardiograph. It can acquire 12-lead ECG signals simultaneously. With an external printer, M2662A can produce ECG report on A4/letter size plain paper, which provides basic auto-measurement of the ECG. A LCD facilitates monitoring signal quality, entering patient ID, and configuring the electrocardiograph. M2662A can store 30 ECG's for printing and transmitting. It provides an infrared interface for printing ECG data on IrDA compatible printers. An RS232 port is also provided to allow transfer of ECG data to fax machine or personal computer with Agilent ECG Manager software.

**3. INTENDED USE**      The M2662A Handheld Electrocardiograph is intended for:

- Acquisition, digitization, recording, and retrieval of conventional diagnostic 12-lead simultaneous ECG waveforms and ECG data
- Recording of limited patient information through keypad
- Performing basic auto-measurement of ECG waveforms and preliminary interpretation of measurements (measurements and diagnostic statements are offered to the physician on an advisory basis only; the physician is asked to review and validate or change the ECG interpretation.)

**4. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS**

The M2662A Handheld Electrocardiograph has the same interpretive cardiograph characteristics as the predicate M1770A Cardiograph. For example, they both contain the same ECG measurements, adult and pediatric analysis programs, software filtering algorithm, ECG basic controls (disable Page Advance in M2662A) and both have the same standardization, DC offset sensitivity, time base and accuracy stability, bandwidth, input dynamic range, digital sampling rate, storage of recorded signals. The M2662A Handheld Electrocardiograph has very similar hardware design as the predicate M1770A Cardiograph. For example, they both use the same CPU, the same ECG data acquisition front end, the same conventional 12 simultaneous lead ECGs, the same electrodes, the same ECG and message display, the same ECG transmission interface. In fact, we would like to say M2662A Handheld Electrocardiograph is a small package of M1770A Cardiograph because it has the same interpretation software also well as similar operating software and hardware.

**8. NON-CLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE**

The substantial equivalence of the M2662A Handheld Electrocardiograph is demonstrated by the following non-clinical testing:

- testing to applicable standards: AAMI EC11, IEC 601-1, IEC 601-2-25, IEC 601-1-2 (EMC)
- Agilent software and performance testing following established test procedures.

**9. CONCLUSIONS FROM NON-CLINICAL TESTING**

Prior to marketing release in the US; M2662A will have completed the testing listed above with acceptable results, demonstrating substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Rob Butler  
Regulatory Affairs Manager  
Agilent Technologies, Inc.  
Healthcare Solutions Group  
3000 Minuteman Road  
Andover, MA 01810-1099

Re: K002459  
Trade Name: Agilent M2662A Handheld Electrocardiograph  
Product Code: DPS  
Class: II (two)  
Dated: October 24, 2000  
Received: October 25, 2000

Dear Mr. Butler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

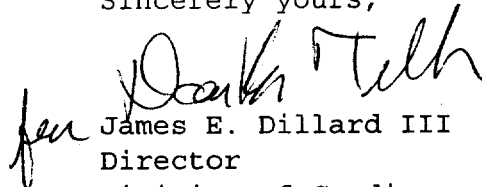
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for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

James E. Dillard III  
Director

Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known):

Device Name: M2662A Handheld Electrocardiograph.

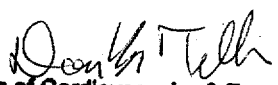
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K002459

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_